

## **REMARKS**

In response to the above Office Action, independent claims 1 and 13 have been amended to include the limitation that the blend of the polyolefin and the polycycloolefin of the intermediate layer of the three or more layers of the claimed container body is composed of blends of "20 to 50 wt% of polyolefin and 50 to 80 wt% of polycycloolefin." Support for this limitation can be found in Example 4 on page 38 where the weight ratio of the two olefins is 50:50 and in Example 6 on page 39 where the weight ratio of the polycycloolefin to the polyolefin is 80:20. See also Examples 4 and 6 in Table 1 on page 41.

Claim 1 has also been amended to delete the unnecessary method steps of filling the container body with a drug solution and instead the flexible container body now contains a drug solution since claim 1 is a product claim. As a result, "parison" in claims 1 and 3 has been changed to "container body" to use consistent language in the claims. Claim 1 has also been amended to included two of the characteristic properties of the functional layer that were inadvertently deleted in the Reply of October 21, 2008. Compare claim 1 of the Reply of January 28, 2008 to this claim. In addition, claims 4-7 have been cancelled for being unnecessary. Amendments have also been made to claim 13 to correct a typographical error and for clarity.

The present inventors have focused on the use of the drug solution filling plastic ampoule of the invention and the fact that it is to be opened by wrenching the holder tab off from the fusion-bonded portion, and have carefully examined how to improve the operability of the plastic ampoule while maintaining sufficient barrier properties. As a result, the present inventors have discovered that the claimed layer structure having an intermediate layer composed of blends of 20 to 50 wt% polyolefin and 50 to 80 wt%

polycycloolefin can achieve the unexpected effects of providing excellent openability, while maintaining barrier properties.

In the Office Action the Examiner rejected claims 1, 3, 11 and 12 under 35 U.S.C. § 103(a) for being obvious over Meierhoefer in view of Peiffer and Itoh. In addition, claims 13 and 15 were rejected under § 103(a) for being obvious over Louviere in view of Peiffer and Itoh. While in both rejections in paragraphs 5 and 33, the Examiner included the references "Herbert et al. (U.S. 6,068,936)" and "Takurou et al. (U.S. 6,042,906)", it is believed this was in error because the references are not of record and nothing was mentioned about them in the Office Action. Thus they have not been considered in this Reply.

As discussed previously, Meierhoefer only describes a vial in which a container body has a single layer made of plastic.

Peiffer relates essentially to a packaging material, twist-wrap film, laminated film or a printed film made out of a polyolefin film. See claim 18 of Peiffer. The film contains at least one layer containing a blend of a polyolefin and a cycloolefin. As an example of the polyolefin film, Peiffer discloses a transparent three-layer film having Outer layers B (the innermost layer and the outmost layer) consisting of a random ethylene-propylene copolymer and a Base layer A (the intermediate layer) consisting of a blend of isotactic polypropylene and norbornene homopolymer (See EXAMPLE 1 in column 11 of Peiffer). The Examiner, therefore, believes it would be obvious to use this three-layer film for the container body of Meierhoefer.

While the Examiner acknowledges that Peiffer lacks the claimed thickness of an intermediate layer being 11.8 to 35.3% of a total thickness of three layers (paragraph 25

of the Office Action), the Examiner believes this would be an obvious modification of Peiffer in view of Itoh which discloses a multi-layer plastic container comprising at least three layers where an intermediate layer of a cyclic olefin is 1:99 to 30:70 of a total thickness which overlaps the claimed range.

Claims 1 and 13, however, now include the limitation that the intermediate layer is composed of blends of "20 to 50 wt% of polyolefin and 50 to 80 wt% of polycycloolefin." Although Peiffer discloses an intermediate layer of a blend of polyolefin and a polycycloolefin, the amount of the polycycloolefin is less than 50%. Specifically, this is in order to provide a polyolefin film which is distinguished by high strength values and an improved barrier action to the passage of water vapor and oxygen and in addition can be suitable for twist wrapping (see Peiffer, column 2, lines 49-53). In this regard, Peiffer teaches that in the cycloolefin polymer (COP)-containing layer, the layer contains at least 50% by weight, preferably 60-99% by weight, of a polyolefin (Column 3, lines 40-46) and that, "in accordance with the invention," the COP is present in an amount of less than 50% by weight, preferably from 1 to 40% by weight. (Column 4, lines 38-44).

In other words, a composition in which the amount of cycloolefin polymer is less than 50% by weight is an "essential feature" of Peiffer's invention that is required to form the desired polyolefin film having excellent flexibility and being suitable for twist wrapping. See also claim 1 of the reference. Consequently, in view of this it could not be said to be obvious to modify the composition of the polyolefin-cycloolefin polymer of Peiffer to encompass Applicants' claimed range of 50 to 80 wt% of the polycycloolefin because the properties required by Peiffer could not be obtained by it. As noted in

M.P.E.P § 2143.01V, prior art cannot be modified if it renders it "unsatisfactory for its intended purpose."

Thus, even if Meierhoefer, Peiffer and Itoh are combined as proposed by the Examiner, the combination does not teach Applicants' invention as now claimed nor could it be modified to meet the claims because Peiffer, which is relied on to show a layer of a blend of a polyolefin and a polycycloolefin, cannot be modified to encompass Applicants' claimed range of the two polymers in the layer for the reasons discussed above.

Accordingly, it is submitted that neither claim 1 nor claims 3, 11 and 12 dependent therefrom are obvious over this combination of references. Its withdrawal as a ground of rejection of these claims is therefore requested.

Regarding claims 13 and 15 and Louviere, this reference is discussed in the previous Reply and the comments about the reference set forth therein are incorporated herein by reference. Because the Examiner also relies on Peiffer in this rejection to show a blend of a polyolefin and a polycycloolefin in an intermediate layer of a three-layer film, for the same reasons expressed above with respect to claim 1, it is submitted that it cannot be relied on to teach or suggest the claimed range of "20 to 50 wt% of polyolefin and 50 to 80 wt% of polycycloolefin" of these two polymers in this layer as now set forth in claim 13.

Accordingly, it is submitted that neither claim 13 nor claim 15 dependent therefrom are obvious over this combination of references.

It is believed claims 1, 3, 11-13 and 15 are now in condition for allowance.

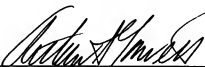
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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